

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the patent application of:

Wen-Cherng Lee, et. al.

Confirmation No. 2278

Application: 10/510.459

Art Unit: 1635

Filed: 8/25/2005

Examiner: Aulaku, Charanjit

Attorney Docket A158 US

For: Tri-Substituted Heteroaryls and Methods of Making and Using the Same

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**APPLICATION FOR PATENT TERM ADJUSTMENT INCLUDING REQUEST
FOR RECONSIDERATION UNDER 37 CFR §1.705(b)**

Dear Sir:

1. This is a request for reconsideration of the patent term adjustment (hereinafter "PTA") which, according to the "Determination of Patent Term Adjustment Under 35 U.S. C. §154(b)" mailed on 12/30/2008 is 487 days. Applicant believes the PTA should be 789 days, if the issue fee is paid on the date that is three months after (i.e. March 30, 2009) the mailing date of the issue fee notice (i.e Dec. 30, 2008) and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of the notice of issue fee due (i.e. July 14, 2009).

2. In compliance with 37 CFR §1.705(b), Applicants' submit herewith the following :

- (1) The fee set forth in 37 CFR §1.18(e); and
- (2) A separate statement of facts involved specifying:
 - (i) The correct patent term adjustment and the basis or basis under §1.702 for that adjustment;
 - (ii) The relevant dates as specified in §§ 1.703 (a) through (e) for which an adjustment is sought and the adjustment as specified in § 1.703(f) to which the patent is entitled;
 - (iii) Whether the patent is subject to a terminal disclaimer and any expiration date specified in the terminal disclaimer; and
 - (iv)(A) Any circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such applications as set forth in §1.704; or
 - (iv)(B) That there were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in §1.704.

3. In accordance with 37 CFR §1.705(b), Applicants' hereby authorize the payment of the fees set forth in 37 CFR §1.705(b)(1). Please charge the fee set forth in 37 CFR §1.18(e) (\$200.00 or the current amount) to our Deposit Order Account No. 503145. Please charge any necessary additional fees or credit any overpayments to our Deposit Order Account No. 503145.

4. A separate statement of the facts in compliance with 37 CFR §1.705(b)(2) providing specifying items in 37 CFR §1.705(b), or number 2 above, is attached and submitted with this application for patent term adjustment and request for reconsideration under 37 CFR § 1.705(b).

Dated 30 March 2009

Respectfully Submitted,



Thomas A. Wootton
Reg. No. 35,004

KALAMAZOO.17920.1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the patent application of:

Wen-Cherng Lee, et. al. Confirmation No. 2278

Application: 10/510,459 Art Unit: 1635

Filed: 8/25/2005 Examiner: Aulaku, Charanjit

Attorney Docket 223255/A158 US/120993

For: Tri-Substituted Heteroaryls and Methods of Making and Using the Same

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT UNDER 37 CFR § 1.705(b)(2)

1. This statement is respectfully submitted in support of the “Application for Patent Term Adjustment Including Request for Reconsideration Under 37 CFR §1.705(b)” for the above-referenced patent application. In view of the following, it is respectfully requested that applicants’ be granted a patent term adjustment (hereinafter “PTA”) of 789 days, if the issue fee is paid on the date that is three months after (i.e. March 30, 2009) the mailing date of the notice of issue fee due (i.e. Dec. 30, 2008) and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of the notice (i.e. July 14, 2009).

2. The patent term adjustment according to the “Determination of Patent Term Adjustment Under 35 U.S. C. §154(b)” mailed on 12/30/2008 is 487 days. This determination is in error for the reasons discussed below, the correct number of days

should be 789 days, if the issue fee is paid on the date that is three months after (30 March 2009) the mailing date of the notice of issue fee due (mailed Dec. 30, 2008) and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of the notice of issue fee due (i.e. 14 July 2009).

3. The factual bases for the above adjustment are set forth as follows:

A. Examination Delays Pursuant to 37 CFR §1.702 and §1.703

Pursuant to 37 CFR §1.702 and §1.703, the period of adjustment of the term of the patent under §1.702 and §1.703 is the sum of the periods calculated under paragraphs §1.703 (a)-(e), to the extent that such periods are not overlapping, less the sum of the periods calculated under §1.704 (the period of Applicant Delay). In the above-referenced application, applicants' are entitled to a period of examination delay equal to the sum of the periods of delay under §1.703(a) and (b) for the reasons set forth below.

(i) “14 Month Delay” Pursuant to §1.703(a)(1)

In accordance 37 CF\$ §1.703(a)(1), applicants' are entitled to a period of patent term adjustment due to the failure by the Office to mail an action under 35 U.S. C. §132 not later than 14 months (*i.e.*, by October 25, 2006) after the actual filing date (hereinafter “14 Month Delay”). As shown on PAIR on the Office's PTA Calculation Sheet, attached, the Office failed to mail an action under 35 U.S.C. § 132 (a Non-Final Rejection) until May 8, 2008. Applicants' are entitled to a period of patent term adjustment beginning on the day after the date that is 14 months after (i.e. October 25, 2006) the date on which the above-referenced application was filed or fulfilled the requirements under 35 U.S.C. § 371(c) (*i.e.*, August 25, 2005) and ending on the date of mailing of an action under 35 U.S.C. §132, (*i.e.*, May 8, 2008.) Accordingly, the period

of patent term adjustment due to the 14 Month Delay by the Office is 561 days, which is in agreement with the period calculated by the Patent Office.

(ii) “Three Years Delay” Pursuant to 37 CFR §1.703(b)

Applicants’ respectfully submit that the Office did not comply with the requirement of 35 U.S.C. §154(b) and 37 CFR §1.702(b), which requires issuance of a patent within 3 years after the date on which the patent application was filed under 35 U.S.C. §111(a). Accordingly, applicants’ are entitled to an additional period of patent term adjustment beginning on August 26, 2008 (the day after the date that is three years after the date on which the above-referenced patent application was filed under 35 U.S.C. § 371(c) of August 25, 2008), and ending on the date of issuance of the patent, which, if the issue fee is paid on the date that is three month after (March 30, 2008) the mailing date of the notice of issue fee due (i.e. Dec. 30, 2008), should result in the patent issuing on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of the notice (i.e. July 14, 2009). This period from Aug 26, 2008 to July 14, 2009 is a period of 323 days.

The proper calculation of adjustment of patent term under *Wyeth v. Dudas* results in a total patent term adjustment of 789 days.

On September 30, 2008, the U.S. District Court for the district of Columbia decided *Wyeth v. Dudas*, No. 07-1492 (D.D.C. September 30, 2008) (“*Wyeth*”) In view of *Wyeth*, applicants’ submit that the captioned patent application is entitled to a total patent term adjustment is 789 days.

In view of *Wyeth*, it is clear that delays under 35 U.S.C. §154(b)(1)(B) (and therefore under 37 C.F.R. §§1.702(b) and 1.703(b)) do not begin until the USPTO has

failed to issue a patent within three years, subject to the exclusions of 35 U.S.C. §154(b)(1)(B)(i)-(iii). In the captioned patent application, the period of adjustment under 37 C.F.R. §1.703(a), ending on May 8, 2008 clearly does not overlap with the period of adjustment under 37 C.F.R. §1.703(b) beginning on the day after August 26, 2008. Accordingly, applicants' are entitled to the period of adjustment under both 37 C.F.R. §1.703(a) and 37 C.F.R. §1.703(b), rather than using the Patent Office calculation which fails to include any time for delay after 3 years from filing or fulfilling the requirements under 35 USC 371(c). As such, applicants' are entitled to a total patent term adjustment (PTA) of 789 days.

(iii) Total Examination Delay Pursuant to 37 CFR §1.703

As set forth in 37 CFR §1.703, the period of examination delay based on the grounds set forth in 37 CFR §1.702 is the sum of the period of change from the 14 Month Delay (561 days), and the maximum period of Three Years Delay (318 days), or 561 plus 323 = 884 days to the extent these periods of delay are not overlapping.

B. “Applicant Delay” Pursuant to 37 CFR §1.704

Pursuant to 37 CFR §1.704 the period of adjustment of the term of the patent due to examination delay is reduced by the period of Applicant Delay. As shown in the PTO's Patent Term Adjustment calculation on PAIR, the Office has calculated a period of Applicant Delay of 94 days.

(i) Applicant Delay for Responding to Restriction Requirement Dated

Applicants' respectfully submit that one period of Applicant Delay of 94 days accrued for the delayed filing of a Response on November 10, 2008. This is consistent with the Patent Term Adjustment calculation shown on PAIR, from the Office.

Accordingly, pursuant to 37 CFR §1.704(b), this 94 day period should be considered an Applicant Delay.

(ii) Calculation of the Total Period of Applicant Delay

In view of the above, applicants' have calculated a total period of Applicant Delay of 94 days which consists of (i) the 94 day period. Accordingly, the total period of this delay is 94 days, which is in agreement with the period calculated by the Office on the PTA Calculation Sheet for Patent Term Adjustment calculation and on PAIR.

C. Calculation of Correct Patent Term Adjustment Pursuant to 37 CFR §1.703 to §1.705

As set forth in 37 CFR §1.704, applicants' are entitled to a period of patent term adjustment equal to the period of examination delays reduced by the period of Applicant Delay. Therefore, applicants' submit that the correct patent term adjustment for the above-referenced patent application is 789 days, which is the difference between the total period of examination delay (561 days plus 323 days equals 884 days) less the Applicant Delay (94 days, less 1 day because it is the day of issue) for a total of 789 days (884 less 94, less 1 is 789 days).

4. In accordance with 37 CFR §1.705(b)(2)(iii), Patent applicants' submit that this patent application is not subject to a terminal disclaimer.

5. In accordance with 37 CFR §1.705(b)(2)(iv)(A) and (B), Patent applicants' do not believe there were any circumstances where there was a failure to engage in reasonable efforts to conclude processing or examination of this application as is set forth in § 1.704

In view of the foregoing, it is respectfully requested that the Application for Patent Term Adjustment and the facts provided in this Statement of Facts be favorably considered and that a corrected Determination of Patent Term Adjustment be issued to reflect a patent term adjustment (PTA) of 789 days.

Dated 30 March 2009

Respectfully Submitted,



Thomas A. Wootton
Reg. No. 35,004

KALAMAZOO.17925.1

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| 10/510,459 | TRI-SUBSTITUTED HETEROARYLS AND METHODS OF MAKING AND USING THE SAME | 03-26-2009::16:51:28 |
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Patent Term Adjustments

Patent Term Adjustment (PTA) for Application Number: 10/510,459

| | | | |
|------------------------------|------------|--------------------------------------|-----|
| Filing or 371(c) Date: | 08-25-2005 | USPTO Delay (PTO) Delay (days): | 561 |
| Issue Date of Patent: | - | Three Years: | - |
| Pre-Issue Petitions (days): | +0 | Applicant Delay (APPL) Delay (days): | 94 |
| Post-Issue Petitions (days): | +0 | Total PTA (days): | 467 |
| USPTO Adjustment(days): | +0 | Explanation Of Calculations | |

Patent Term Adjustment History

| Date | Contents Description | PTO(Days) | APPL(Days) |
|------------|--|-----------|------------|
| 12-30-2008 | Mail Notice of Allowance | | |
| 12-27-2008 | Document Verification | | |
| 12-27-2008 | Notice of Allowance Data Verification Completed | | |
| 12-22-2008 | Date Forwarded to Examiner | | |
| 11-10-2008 | Response after Non-Final Action | | 94 |
| 11-10-2008 | Request for Extension of Time - Granted | | ♦ |
| 05-08-2008 | Mail Non-Final Rejection | 561 | |
| 05-07-2008 | Non-Final Rejection | | ♦ |
| 05-16-2006 | Information Disclosure Statement considered | | ♦ |
| 05-01-2008 | Case Docketed to Examiner in GAU | | ♦ |
| 10-09-2007 | Miscellaneous Incoming Letter | | ♦ |
| 05-16-2006 | Information Disclosure Statement (IDS) Filed | | ♦ |
| 05-16-2006 | Information Disclosure Statement (IDS) Filed | | ♦ |
| 01-17-2006 | IFW TSS Processing by Tech Center Complete | | ♦ |
| 01-17-2006 | Case Docketed to Examiner in GAU | | ♦ |
| 08-25-2005 | Reference capture on IDS | | ♦ |
| 12-24-2005 | Cleared by OIPE CSR | | ♦ |
| 12-23-2005 | Cleared by OIPE CSR | | ♦ |
| 12-23-2005 | Cleared by OIPE CSR | | ♦ |
| 12-23-2005 | Cleared by OIPE CSR | | ♦ |
| 12-21-2005 | Cleared by OIPE CSR | | ♦ |
| 12-21-2005 | Cleared by OIPE CSR | | ♦ |
| 12-21-2005 | Cleared by OIPE CSR | | ♦ |
| 12-21-2005 | Cleared by OIPE CSR | | ♦ |
| 08-25-2005 | 371 Completion Date | | ♦ |
| 12-14-2005 | Application Dispatched from OIPE | | ♦ |
| 12-14-2005 | Notice of DO/EO Acceptance Mailed | | ♦ |
| 08-25-2005 | Additional Application Filing Fees | | ♦ |
| 08-25-2005 | A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applic | | ♦ |